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| 09/944,209      | 09/04/2001  | Roland Callens       | 32232-175096        | 4220             |

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[REDACTED] EXAMINER

MAIER, LEIGH C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1623     | 4            |

DATE MAILED: 04/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
09/944,209

Applica...  
Callens

Examiner  
Leigh Maier

Art Unit  
1623



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1)  Responsive to communication(s) filed on \_\_\_\_\_
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- 4)  Claim(s) 7 and 11-17 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 7, 11, 12, and 16 is/are rejected.
- 7)  Claim(s) 13-15 and 17 is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.
- 12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. 08/257,292.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15)  Notice of References Cited (PTO-892)      18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      19)  Notice of Informal Patent Application (PTO-152)
- 17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3      20)  Other: \_\_\_\_\_

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## DETAILED ACTION

### *Priority*

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

If applicant desires priority under 35 U.S.C. 119 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Further regarding the claim for priority, in the remarks accompanying the pre-amendment, Applicant indicates that the instant application is a divisional application of 09/502,561, now U.S. Patent No. 6,310,178. However, in the application transmittal papers, the boxes for both "Divisional" and "Continuation" are checked. It is noted that claim 7 is an

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originally filed claim comprising the non-elected group resulting from the restriction requirement in the parent. Claims 11-17 are not originally filed claims, as evidenced by the pre-amendment, filed September 4, 2001. These claims were not withdrawn from consideration as a result of a previous restriction requirement but were derived from claims that were prosecuted in the parent.

***Claim Objections***

Claim 11 is objected to because of the following informalities: The structural formula comprises a moiety incorrectly depicted by “HN<sub>2</sub>” rather than “NH<sub>2</sub>” for the terminal amine group. This formula also appears to be missing a line indicating a bond between “Pro” and the terminal amine. Appropriate correction is required.

Claim 16 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. The independent claim, claim 11, defines the linear carbon chain as being formed by exactly two, not a range, of carbon atoms. Therefore, the number of carbons in the chain cannot be further limited.

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***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by each of a number of references, set forth below:

- WILCHEK et al (Biochem., 1987) discloses  $\beta$ -Ala-N<sup>e</sup>-Lys-urea, a compound consistent with the formula depicted in the claim. See Figure 6 at page 2158.
- FUNG et al (US 5,032,577) discloses a renin inhibitor, a compound which is consistent with the formula depicted in the claim. See example 206 at col 50.
- AYRAL-KALOUSTIAN et al (US 5,312,831) discloses compounds consistent with the formula depicted in the claim. See examples 28, 29, 32, and 36.
- KESSLER et al (Pept. Chem., 1988) discloses a lysine “dimer” that is consistent with the formula of the formula depicted in the claim. See first compound in Fig. 4. Because the structure is not clear from this drawing in the original reference, Applicant is also provided with the CAS abstract and the structure of the compound.
- TUOMANEN et al (Antimicrob. Agents, Chemother., 1984) discloses a lysine- $\beta$ -lactam conjugate that is consistent with the formula depicted in the claim. See compound 1 in Table 1. Applicant’s broad definition of “amino acid” allows for this  $\beta$ -lactam to be considered as such.

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Claims 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by SCHWERTNER et al (US 4,045,556).

SCHWERTNER discloses orotyl-histidyl-prolinamide, a compound consistent with the formula depicted in the claim. See col 13, lines 40-42. Thus, the claims are anticipated.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.d. 887, 225 USPO 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.d. 937, 214 USPO 761 (CCA 1982); *In re Vogel*, 422 F.d. 438, 164 USPO 619 (CCA 1970); and, *In re Thorington*, 418 F.d. 528, 163 USPO 644 (CCA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 12 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,310,178 in view of SCHWERTNER et al (US 4,045,556).

Claim 2 of the ‘178 patent is drawn to peptides similar in structure to those of the instant claim. The peptides of the ‘178 claim differ from the instant peptides in that the heterocycle comprising the “A” variable is a 7-membered ring, whereas the corresponding heterocycle of the

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instant peptides is a 6-membered ring. Therefore, the instant peptides are homologs of those of claim 2 of the '178 patent.

SCHWERTNER teaches orotyl-histidyl-prolinamide as set forth above. In this compound, the orotyl moiety, corresponding to the heterocycle comprising the "A" variable, is a 6-membered ring. This compound is disclosed as having anti-depressive activity.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have prepared the peptides of the instant invention. The artisan would have been motivated to prepare these homologs of those in the '196 patent for the art-disclosed utility in treating depression.

*Allowable Subject Matter*

Claims 13-15 and 17 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Other than the carbonyl substituent in orotyl-histidyl-prolinamide, SCHWERTNER teaches only alkyl substituents on what would correspond to the "A" variable. The reference does not teach or suggest ring substitution by heteroatom-containing substituents recited in these claims.

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***Examiner's hours, phone & fax numbers***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Tuesday, Wednesday, or Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Johann Richter (703) 308-4532, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.



Leigh C. Maier  
Patent Examiner  
April 5, 2002